

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 124118x342/60 RTM | <div style="display: flex; justify-content: space-between;"> <div>FOR FURTHER ACTION</div> <div>See Form PCT/IPEA/416</div> </div> | |
| International application No. PCT/NZ2004/000231 | International filing date <i>(day/month/year)</i> 23 September 2004 | Priority date <i>(day/month/year)</i> 23 September 2003 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61D 1/02, A01J 3/00 | | |
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| 1. | This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. |
| 2. | This REPORT consists of a total of 3 sheets, including this cover sheet. |
| 3. | This report is also accompanied by ANNEXES, comprising: <div style="margin-left: 20px;"> a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of 4 sheets, as follows: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> </div> <div style="margin-left: 20px;"> b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). </div> |
| 4. | This report contains indications relating to the following items: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application </div> |

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| Date of submission of the demand 8 April 2005 | Date of completion of the report 24 October 2005 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer XAVIER GISZ Telephone No. (02) 6283 2064 |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/NZ2004/000231

Box No. 1 Basis of the report

With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages 1-22 as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* 23-26 received by this Authority on 18 October 2005 with the letter of 18 October 2005

pages* received by this Authority on with the letter of

☒ the drawings:

pages 1/5 - 4/5 as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☒ the drawings, sheets/figs 5/5 figure 6

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/NZ2004/000231

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-35 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-35 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-35 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

Novelty (N) and Inventive Step (IS)

Claims 1-35 meet the criteria set forth in PCT Articles 33(2) and 33(3) for novelty and inventive step. The prior art published before the priority date does not disclose or obviously suggest a device that resides entirely within a teat streak canal wherein the surface of the device is contoured to allow the formation of an endogenous keratin plug as defined in the claims.

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WHAT WE CLAIM IS:

1. A device capable of insertion into a teat orifice wherein the device is capable of being held in position entirely within the teat streak canal once inserted therein, and wherein the surface of the device is contoured to integrate with endogenous keratin to form a composite plug.
2. The device as claimed in claim 1 wherein the device is configured to deliver one or more treatment substances to the streak canal.
3. The device as claimed in claim 2 wherein the device is configured to deliver said one or more treatment substances for a period of time necessary for endogenous keratin plugs to form.
4. The device as claimed in any one of claims 1 to 3 wherein the device is configured to degrade over time.
5. The device as claimed in any one of claims 1 to 4 wherein the device is configured to act as a physical barrier to prevent the unwanted passage of substances through the streak canal.
6. The device as claimed in any one of claims 1 to 5 wherein the device is made of a preformed matrix.
7. The device as claimed in claim 6 wherein the matrix is silicone.
8. The device as claimed in claim 6 or claim 7 wherein one or more treatment substance(s) are contained within the inner core of the device.
9. The device as claimed in claim 6 or claim 7 wherein the matrix is impregnated with said one or more treatment substances.

10. The device as claimed in claim 9 wherein said one or more treatment substances are delivered by diffusion from the matrix.
11. The device as claimed in claim 9 wherein said one or more treatment substances are delivered through dissolution of the matrix.
12. The device as claimed in any one of claims 2 to 11 said one or more treatment substances are selected from a list including antibiotics, antibacterial substances, tissue growth enhancers, vitamins, minerals, hormones, oxytocin, prolactin, and healants.
13. The device as claimed in any one of claims 1 to 12 wherein the device is configured to withstand the build up of milk pressures immediately post-drying off without the device being ejected.
14. The device as claimed in any one of claims 1 to 13 wherein the device is configured to be dislodged from the streak canal by the milk pressure generated as a consequence of lactogenesis.
15. The device as claimed in any one of claims 1 to 14 wherein the device includes one or more surface features to enhance the retention of the device.
16. The device as claimed in claim 15 wherein said one or more surface features include one or more grooves.
17. The device as claimed in claim 15 or claim 16 wherein said one or more surface features include a spiral thread.
18. The device as claimed in any one of claims 15 to 17 wherein said one or more surface features include a plurality of protrusions.

19. The device as claimed in any one of claims 15 to 18 wherein said one or more surface features are configured so as to cause minimal dislodgment of keratin at insertion and integrate with endogenous keratin.
20. The device as claimed in any one of claims 1 to 19 wherein the device is configured to allow the surrounding smooth muscle layer of the streak canal to form naturally and without irritation around the body of the device.
21. The device as claimed in any one of claims 1 to 20 wherein the device includes a recess which extends at least part of the axial length of the device.
22. The device as claimed in claim 21 wherein the recess acts as a reservoir to hold one or more treatment substances.
23. A device as claimed in claim 21 or claim 22 wherein the recess extends substantially the axial length of the device to form a conduit.
24. The device as claimed in claim 23 wherein the conduit permits the passage of instruments, applicators, other devices, one or more treatment substances.
25. The device as claimed in claim 23 wherein the conduit allows the passage of milk.
26. The device as claimed in any one of claims 23 to 25 wherein the conduit allows the animal to be milked while the device is in position.
27. A device as claimed in any one of claims 23 to 26 wherein the external aperture of the conduit exerts control over teat orifice dilation and/or closure to control and/or improve milk harvesting.

28. The device as claimed in claim 27 wherein the aperture has a two-way valve system.
29. The device as claimed in claim 27 or claim 28 wherein the aperture is operated by vacuum pulsation.
30. The device as claimed in claim 27 or claim 28 wherein the aperture is operated by an inductive pulse.
31. A method of treating an animal using a device as described in any one of claims 1 to 30.
32. A method of treating an animal using a device capable of insertion into a teat orifice

characterised by the step of

Inserting said device into a teat orifice during involution, the device capable of being held in position entirely within the teat streak canal once inserted therein and wherein the surface of the device is contoured to allow the formation of an endogenous keratin plug.
33. A method of treating an animal as claimed in claim 32 including the further step of delivering one or more treatment substances to the streak canal.
34. A device substantially as described herein with reference to and as illustrated by the accompanying description and drawings.
35. A method of treating an animal substantially as described herein with reference to and as illustrated by the accompanying description and drawings.